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NDMA
NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

Better Health Through Responsible Self-Medication

April 17, 1998 '98 APR 20 A8:01

Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm. 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Re: International Drug Scheduling; Convention on Psychotropic Substances; Dihydroetorphine; Ephedrine; Remifentanil; Isomers of Psychotropic Substances -- Docket No. 98N-0148, 63 Fed. Reg. 13258, NDMA Comments

Dear Sir or Madam:

On March 18, 1998, the Food and Drug Administration (FDA) published the above-referenced notice requesting comments concerning abuse potential, actual abuse, medical usefulness, and trafficking of dihydroetorphine, ephedrine, and remifentanil. The notice stated this information would be considered in preparing a U.S. response to a World Health Organization (WHO) notification.

The Nonprescription Drug Manufacturers Association (NDMA) is the national association representing manufacturers and distributors of nonprescription, or over-the-counter (OTC), medications. NDMA members account for some 95% of retail sales of OTC medicines in the U.S. NDMA has been active on a number of aspects concerning ephedrine, including with FDA, with the Drug Enforcement Administration (DEA), with the Congress, and with state legislatures and regulatory bodies. Our activities have included those aimed against chemical diversion and drug abuse.

Summary

Any assessment by the World Health Organization recommending that ephedrine be scheduled or controlled under the United Nations Convention on Psychotropic Substances would

98N-0148 D C2

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be misplaced and would run counter to well developed U.S. policies. FDA should take a strong stance against any such action by the World Health Organization for at least five reasons:

1. FDA has already found that ephedrine and certain ephedrine combination drug products are generally recognized as safe and effective when properly labeled for OTC use. There are no data to question these approved uses.

2. Congress and the Drug Enforcement Administration already have a framework in place under three Acts to limit large scale diversion of ephedrine for the manufacture of illicit substances, while maintaining consumer accessibility to legitimate OTC products -- specific goals which would be undermined by the UN Convention on Psychotropic Substances.

3. Individual states in the U.S. have focused on similar themes to federal activity, not of the type envisioned under the UN Convention.

4. The U.S. framework concerning ephedrine more closely parallels a *different* UN Convention -- the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which already includes ephedrine, and should be the focus for current enforcement activity.

5. In contrast, the focus of the UN Convention on Psychotropic Substances is *not* on precursor chemicals, but rather on risks and benefits of substances themselves.

NDMA requests:

- FDA should advocate and clearly communicate to WHO the U.S. position embodied in the Comprehensive Methamphetamine Control Act and FDA's bronchodilator and anorectal monographs: Continued consumer accessibility to ephedrine-containing products remains an important objective.

- FDA should forward its well-founded, thoroughly reviewed stance on ephedrine's safety as a nonprescription medicine to WHO, noting the ingredient's usefulness as a bronchodilator and anorectal product.

I. FDA Has Already Found That Ephedrine and Certain Ephedrine Combination Drug Products Are Generally Recognized as Safe and Effective When Properly Labeled for OTC Use. There Are No Data to Question These Approved Uses.

Ephedrine has a long and well-established safety and effectiveness record for its intended use as a nonprescription bronchodilator. As FDA noted in its Final Monograph on Bronchodilator Drug Products:

> OTC availability . . . provides asthmatics ready access to this essential medication without the need for additional visits to a physician's office or to a hospital emergency room. This availability especially benefits those asthmatics whose attacks are triggered by common environmental factors (primarily by exertion, anxiety, exposure to cold, etc.) when immediate use may be essential. In addition, physician-diagnosed asthmatics who do not have easy access to medical care will continue to benefit from OTC use.[1]

FDA came to this conclusion, as did the OTC Review expert panel which reviewed available data for OTC bronchodilator products, fully aware that there are risks associated with self-diagnosis and self-treatment of asthma.[2] But FDA, agreeing with the panel's recommendation, found the drugs safe and effective for OTC use when taken as directed and when appropriately labeled.[3] While a November 14, 1994, joint meeting of FDA's Pulmonary-Allergy and Nonprescription Drugs Advisory Committees included discussion of ephedrine and a number of speakers expressed concerns about the ingredient in OTC products, the Committees did not address the particular question of whether FDA should revoke ephedrine's Monograph status. Further, at an August 27, 1996 meeting of the FDA Food Advisory Committee, a Center for Drug Evaluation and Review official stated that FDA has no reports of significant adverse reactions associated with ephedrine-containing OTCs used for their intended bronchodilator use.

FDA has also found ephedrine as safe and effective for other uses. In the Final Monograph for Anorectal Drug Products for OTC Use, FDA found ephedrine sulfate in appropriate cream, lotion, or ointment concentrations generally recognized as safe and effective to temporarily reduce swelling associated with irritation in hemorrhoids.[4]

In the current context, FDA's existing determinations -- that properly labeled ephedrine is safe and effective for a number of specific OTC uses -- are precisely the type of information that

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[1]51 Fed. Reg. 35326, 35327 (October 2, 1986).

[2]See 51 Fed. Reg. 35327. The Cough-Cold Panel and FDA considered both bronchodilator products in general and specifically ephedrine. See 51 Fed. Reg. 35331.

[3]Id. (The Final Monograph on bronchodilator OTC products is codified in 21 C.F.R. Part 341.)

[4]21 C.F.R § 346.12 (as announced in 55 Fed. Reg. 31776 (August 3, 1990)).

should be drawn to WHO's attention as it prepares its assessment for the United Nations (UN) Commission on Narcotic Drugs on ephedrine. The UN Convention on Psychotropic Substances is clear on this point: "[T]he World Health Organization shall communicate to the Commission an assessment of the substance, including the extent or likelihood of abuse, the seriousness of the public health and social problem *and the degree of usefulness of the substance in medical therapy* . . ." (emphasis added).[5]

FDA and others have noted that some ephedrine-containing products have been promoted for uses as stimulants, for weight control, or for muscle enhancement.[6] But such claims are already outside of FDA's Final Monograph and a violation of existing law. FDA has the authority to move against such uses of ephedrine. The Federal Trade Commission, with which FDA has a close working relationship, also has the authority to take action against companies that illegally promote ephedrine products for unapproved uses.[7] Given the existing enforcement mechanisms against illegal products and claims available to FDA, FTC, and DEA (as discussed in section II below), these already illegal practices should not be considered in the benefit-risk assessment of appropriately labeled ephedrine-containing OTC products.

II. Congress and the DEA Already Have a Framework in Place Under Three Acts to Limit Large Scale Diversion of Ephedrine for the Manufacture of Illicit Substances While Maintaining Consumer Accessibility to Legitimate OTC Products -- Specific Goals Which Would Be Undermined by the UN Convention on Psychotropic Substances.

NDMA strongly supports the national goal of fighting drug abuse, including opposition to the diversion of legitimate products for use in the production of other illicit substances. As a result, NDMA supported adoption of the Chemical Diversion and Trafficking Act of 1988, the Domestic Chemical Diversion Control Act of 1993, and, most recently, the Comprehensive Methamphetamine Control Act of 1996 (CMCA).

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[5]UN Convention on Psychotropic Substances, Article 2, para. 4(b).

[6]See 60 Fed. Reg. at 39644.

[7]See Federal Trade Commission Act, section 5 (15 U.S.C. § 45).

NDMA recognizes that precursor chemicals, including ephedrine, have been diverted to clandestine methamphetamine production and remains committed to working with Congress and the DEA to guard against such diversion. DEA has extensive powers under the three Acts mentioned to address diversion at all levels, particularly the rogue companies operating on the fringes of legitimate commerce that import bulk precursor chemicals, formulate them into dosage units, and distribute those units in large quantities to persons engaged in methamphetamine production.[8] But that process takes place apart from the distribution of legitimate OTC products marketed by NDMA members through traditional retail outlets. Legitimate OTC products are *not* a significant part of the problem -- a fact recognized by DEA.

In passing the three Acts mentioned, Congress clearly intended to minimize the impact of the laws on the legitimate OTC ephedrine drug industry by creating in the CMCA a special retail exemption for sales below a threshold of certain OTC ephedrine products: DEA has proposed a retail exemption for single transaction sales of ephedrine combination products below 24 grams.[9]

Even more clearly, after thorough consideration, Congress did *not* make ephedrine-containing products subject to a controlled substance schedule. Instead, the thrust of Congress' intent and DEA's activities have been on large-scale diversion of ingredients as precursors for illicit production -- *not* on abuse of ephedrine in and of itself. Yet controlled substance scheduling is exactly the type of control envisioned by the UN Convention on Psychotropic Substances. In weighing the benefits and risks of consumer access to safe and effective OTC ephedrine products against diversion risks, the U.S. government position embodied in the CMCA (as well as in FDA's bronchodilator and anorectal monographs discussed in section I) is clear:

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[8]DEA has noted that the CMCA replaces rules proposed by DEA in this area with a more comprehensive system of controls relating to distribution, importation, and exportation of combination ephedrine products (single ingredient ephedrine products were already covered under the Domestic Chemical Diversion Control Act of 1993) and two other nonprescription drug ingredients, along with other strong tools to attack illicit traffic. See 62 Fed. Reg. 52294, 52296 (October 7, 1997). The CMCA includes a number of provisions summarized in Attachment A.

[9]See DEA Proposed Rule re: Implementation of the Comprehensive Methamphetamine Control Act of 1996, 62 Fed. Reg. 52294 (October 7, 1997).

continued consumer accessibility to these products remains an important objective. We request that FDA advocate this position and clearly communicate it to WHO as it conducts its assessment on ephedrine.

III. U.S. Individual State Activity Has Focused on Similar Themes to Federal Activity, Not of the Type Envisioned Under the UN Convention.

A number of U.S. states have looked at the issues of ephedrine diversion and misuse for indications not approved by FDA. NDMA member company products containing ephedrine have *not* been identified with illegal, unapproved uses. In fact, many states have exempted properly labeled and packaged ephedrine-containing products when placing restrictions on ephedrine.[10] The states, like the federal government, have recognized that proposals which would limit the sales of all ephedrine products would create great difficulty for people such as asthma sufferers in obtaining nonprescription medicines. In addition to the unapproved uses states have addressed, implicit in these state actions is the central theme of federal activity: at the core of the problem is diversion. Diversion can best be addressed through tools other than across-the-board restrictions of the type envisioned under scheduling through the UN Convention on Psychotropic Substances.

IV. The U.S. Framework Concerning Ephedrine More Closely Parallels the Types of Controls Envisioned Under the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, Which Already Includes Ephedrine, and Should Be the Focus for Current Enforcement Activity.

Ephedrine is already included in the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.[11] One focus of this Convention is to monitor precursors and

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[10]For example, Florida, Idaho, Iowa, Louisiana, New Mexico, Oregon, among other states, place single ingredient ephedrine or combination ephedrine products on prescription status or on controlled substance schedules, but exempt formulations in compliance with FDA requirements or approvals. Attachment B summarizes state laws in this area.

[11]See United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, Annex Table I, 28 I.L.M. 493 (1989).

other chemicals used in the manufacture of illicit substances.[12] The Convention matches well with existing U.S. government policies -- policies enacted by the Congress as recently as 1996 (as described in section II). Precisely on point is the Convention's Article 12. Article 12 deals with precursors, and includes a range of tools to monitor trade and combat diversion:

- Systems to monitor international trade, including identifying suspicious transactions;
- Authority for seizure where there is sufficient evidence that a listed substance is used in illicit manufacture;
- Notification among parties;
- Required labeling details for shipping documents in import/export; and
- Mandated record-keeping, among others.[13]

Even if ephedrine diversion and use as a precursor in the illicit manufacture of controlled substances is increasing, increased attention to enforcing *this* Convention is the appropriate response.[14] Creating additional controls makes no sense if existing controls have not been fully exercised and brought to the attention of the parties to the UN Illicit Traffic Convention.

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[12]See UN Convention Against Illicit Traffic, supra. (One of the declarations of the preamble notes that a reason for adopting the Convention was "[c]onsidering that measures are necessary to monitor certain substances, including precursors, chemicals and solvents, which are used in the manufacture of narcotic drugs and psychotropic substances. . . .)

[13]See UN Convention Against Illicit Traffic, Article 12 (9)(a) through (e), supra.

[14]In contrast to any assertion that ephedrine diversion has increased, the DEA proposed rule to implement the Comprehensive Methamphetamine Control Act of 1996 includes figures indicating that, since passage of the Domestic Chemical Diversion Control Act of 1993, the percentage of methamphetamine lab seizures where ephedrine has been identified as the source material has gone down. See 62 Fed. Reg. 52294, 52295 (October 7, 1997).

V. The Focus of the UN Convention on Psychotropic Substances Is Not on Precursor Chemicals, But Rather on Risks and Benefits of Substances Themselves.

In contrast to the UN Illicit Traffic Convention, the focus of the UN Convention on Psychotropic Substances is *not* on precursor chemicals. Its focus is on the risks of substances themselves, most notably in the description of WHO's role in making medical and scientific assessments. The WHO role is clear. The WHO assessment criteria state that if WHO finds that a substance has the capacity to produce:

> i. (1) A state of dependence, and (2) Central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behavior or perception or mood, or ii. Similar abuse and similar ill effects as a substance in Schedule I, II, III, or IV, and
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> (b) That there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control, the World Health Organization shall communicate to the Commission an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy. . . .[15]

Further clarifying the type of evidence that triggers a WHO assessment, the Commentary to the Convention on Psychotropics Substances notes that: "It is apparent that only a *significant* health problem appears to be a 'public health' problem as this phrase is used by the Vienna Convention. . . ."[16] As discussed earlier, we are not aware of a significant problem with legitimate ephedrine-containing nonprescription medicines. FDA, after extensive review, has already found that ephedrine is generally recognized as safe and effective for more than one nonprescription use. It is clear that ephedrine does *not* pose the type of problem addressed by the Convention on Psychotropic Substances.

We request that FDA forward its well-founded, thoroughly reviewed stance on ephedrine's safety as a nonprescription medicine to the WHO. In so doing, FDA should note the

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[15]United Nations Convention on Psychotropic Substances, Article II, 4.

[16]See Commentary on the Convention on Psychotropic Substances, 1971, United Nations Publication E.76.XI.5, 46.

ingredient's usefulness as a bronchodilator and an anorectal -- usefulness of the type the Convention on Psychotropic Substances mandates that WHO include in any assessment.

VI. Conclusion.

Any assessment by WHO recommending that ephedrine be scheduled or controlled under the UN Convention on Psychotropic Substances would run counter to U.S. policies. Such policies are well-founded on FDA's OTC Review concluding ephedrine is generally recognized as safe and effective, and on the intent of Congress that ephedrine-containing nonprescription medicines be available to consumers without a prescription and not on controlled substance schedules. The Comprehensive Methamphetamine Control Act, U.S. state laws to limit diversion, DEA enforcement tools against diversion, FDA and FTC enforcement tools against illegal claims, and the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances -- all of these are already in place to protect the safety of American consumers and other consumers around the world. FDA should communicate this clear message to WHO as the WHO Expert Committee on Drug Dependence assesses ephedrine.

Thank you for considering our views.

Sincerely,

David C. Spangler
Vice President - International
& Assistant General Counsel

Attachment: A. Summary of the Comprehensive Methamphetamine Control Act of 1996, NDMA, April 1998
B. Summary of State Regulation of Ephedrine, Pseudoephedrine, and Phenylpropanolamine, NDMA, October 1997

cc: Stuart L. Nightingale, M.D., Associate Commissioner for Health Affairs, FDA
Nicholas P. Reuter, Office of Health Affairs, FDA

ephd-who.fda/dcs

Nonprescription Drug Manufacturers Association

Summary of the Comprehensive Methamphetamine Control Act of 1996

On October 3, 1996, President Clinton signed into law the Comprehensive Methamphetamine Control Act of 1996 (CMCA). The new law broadens controls on certain chemicals used in the production of methamphetamine, increases penalties for the trafficking and manufacture of methamphetamine and listed chemicals, and expands regulatory controls to include the distribution of certain lawfully marketed drug products which contain ephedrine (EPH), pseudoephedrine (PSE), and phenylpropanolamine (PPA).

The following is a brief summary of major provisions of the CMCA:

- Makes the possession of list I chemicals a crime in instances where the chemicals were obtained under a registration that was suspended or revoked.

- Extends Federal "long arm" jurisdiction for certain controlled substance offences to included the manufacture and distribution of listed chemicals outside of the U.S. with intent to illegally import them. Therefore, violations committed outside the country shall be subject to prosecution in the U.S.

- Establishes higher maximum penalties for the manufacture, import, export, possession or distribution of chemicals or equipment used in methamphetamine production. This provision increases the maximum penalties to 10 years for a first offense and 20 years for a subsequent offense. The law also directs the sentencing commission to review and amend sentencing guidelines for methamphetamine offenses and to enhance penalties for offenses involving list I chemicals.

- Imposes a civil fine of up to $250,000 for any firm which distributes a laboratory supply (defined as a listed chemical or any chemical or equipment which the Attorney General publishes on a special surveillance list) to a person who uses it in a clandestine lab, where the distribution is with "reckless disregard" for the intended illicit use. A rebuttable presumption of "reckless disregard" will be found if a firm sells a laboratory supply to a particular customer after receiving written notification from DEA that this customer has diverted laboratory supplies for illicit uses in the past.

- Enhances current injunctive authority of the Attorney General and establishes new injunctive authority relating to various violations of the Controlled Substances Act (CSA) including certain violations relating to listed chemicals and other chemicals, products, and equipment used in the illicit manufacture of controlled substances.

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- Includes provisions for the restitution of cleanup costs by a defendant convicted of offenses involving clandestine methamphetamine labs.

- Establishes advisory panels and task forces to evaluate methamphetamine education and prevention programs, to monitor methamphetamine abuse within the U.S., and to develop programs to aid industry in better identifying suspicious orders.

- Adds iodine and hydrochloric gas to list II.

- Effective October 3, 1997, the law subjects transactions involving PSE and PPA to the registration, recordkeeping and reporting requirements of the CSA. However, the law creates a "safe harbor" (exemption) for the retail sale of "ordinary over-the-counter products" that contain PSE and PPA. In order to be included in the safe harbor, the product must meet two requirements: 1) the package must contain not more than 3 grams of the base ingredient, and 2) the product must be in blister packs of not more than two tablets per blister (unless use of the blister pack is technically impossible, such as liquids). For products not packaged in accordance with the "safe harbor" exemption as of October 3, 1997, retailers will be required to register with DEA if they sell more than 24 grams in a single transaction and to keep records of such transactions. Retailer is defined as a grocery store, general merchandise store, drug store, or other entity or person whose activities relating to PSE and PPA are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

- DEA can revoke the safe harbor for retail sales and impose a single transaction limit of 24 grams for all products containing PSE or PPA if it finds that there is a significant number of safe harbored products sold by retailers that are being widely used as a significant source of precursor chemicals for illegal manufacture of methamphetamine.

- Effective October 3, 1996, ephedrine-combination products are subject to the 24 gram, single-transaction limit for registration, recordkeeping and reporting under the CSA. However, DEA has issued an interim regulation temporarily exempting retail distributors of ephedrine-combination products from the registration requirements for single transaction sales below 24 grams of ephedrine base, and has issued a proposed rule to make the exemption permanent.

- Mail order distributors must report to DEA all sales of EPH, PSE and PPA to "non-regulated" persons on a monthly basis.

KJK/ds-4/17/98

Nonprescription Drug Manufacturers Association

SUMMARY OF STATE REGULATION OF
EPHEDRINE, PSEUDOEPHEDRINE & PHENYLPROPANOLAMINE

Revised 10/30/97

State	Type of Restriction, Citation and Date Enacted	Sales Restrictions on Single-Ingredient Ephedrine	Sales Restrictions on Combination Ephedrine Products	Other Restrictions on Ephedrine, PSE and PPA
Alabama	n/a	None	None	None
Alaska	n/a	None	None	None
Arizona	By Statute: Ariz. Rev. Stat. § 36-2516.A.3 (1990).	Controlled Substance Schedule V for single ingredient products.	None	None
Arkansas	By Regulation: Dept. of Health Rule; see Ark. Controlled Substance List (effective February 1996). By Statute: Act 565 of 1997 (not yet codified) Ark. Code Ann. § _____ (1997).	Controlled Substance Schedule V (including combos with insignificant amounts of other active ingredients).	None	Unlawful to possess more than 5 grams of ephedrine with exemption for retailers and health care providers. Unlawful to possess ephedrine, pseudoephedrine or PPA with intent to manufacture methamphetamine.
California	By Statute: Cal. Health & Safety Code § 11100(a)(16) (1996); Cal. Health & Safety Code § 11383 (1993). Cal. Health & Safety Code §_____ (1997).	Reporting of transactions involving single ingredient ephedrine in solid dosage form.	None	Prohibits possession of ephedrine or pseudoephedrine with intent to manufacture methamphetamine. Requires recordkeeping & reporting of threshold transactions of EPH, PSE & PPA.
Colorado	n/a	None	None	None
Connecticut	n/a	None	None	None
Delaware	n/a	None	None	None
District of Columbia	n/a	None	None	None
Florida	By Statute: F. Stat. Ann. § 499.033 (1995). Emergency Order of Dept. Of Health & Rehab. Services (April 1996).	Prescription drug status for any ephedrine (single ingredient or in combination); no exemption for single ingredient ephedrine.	Prescription drug status for any ephedrine (single ingredient or in combination), with statutory exemptions for specific ingredient formulations in compliance with FDA.	Prohibits advertising or labeling of ephedrine products for unapproved uses. Ban on sale of ephedrine-containing dietary supplements.

(Continued. . . .)

State	Type of Restriction, Citation and Date Enacted	Sales Restrictions on Single-Ingredient Ephedrine	Sales Restrictions on Combination Ephedrine Products	Other Restrictions on Ephedrine, PSE and PPA
Georgia	n/a	None	None	None
Hawaii	Local ordinance: City Ordinance for City of Honolulu (1996).	Prohibits sale of any ephedrine-containing product to anyone under 18 years old.	Prohibits sale of ephedrine-containing product to anyone under 18 years old.	Prohibits sale of ephedrine-containing dietary supplements but exempts FDA-approved OTC drugs from prohibition.
Idaho	By Statute: Idaho Code § 37-2707. By Regulation: Rule No. 158.01 (revised 1994).	Controlled Substance Schedule II; exemption for products prepared for over-the-counter distribution. Prescription drugs status for ephedrine with list of exempted products by brand name.	Controlled Substance Schedule II; exemption for products prepared for over-the-counter distribution. Prescription drugs status for ephedrine with list of exempted products by brand name.	None
Illinois	By Statute: 720 Ill. Rev. State. Ch 570, ¶ 210(g) (1995).	Controlled Substance Schedule IV (including combos with insignificant amounts of other active ingredients).	None	None
Indiana	n/a	None	None	None
Iowa	By Statute: Iowa Code § 124.401 (1996). Iowa Code § 124.212(5) (1997).	Controlled Substance Schedule V with exemptions for specific product formulations; no exemption for single ingredient products.	Controlled Substance Schedule V with exemptions for two specific product formulations.	Prohibits sale or distribution of ephedrine or pseudoephedrine with knowledge that drugs will be used to manufacture an illicit substnace or for other than a medicinal use; prohibits possession of those drugs with intent to manufacture an illicit substance.
Kansas	By Statute: Kan. Stat. Ann. § 65-4113	Controlled Substance Schedule V.	None	None
Kentucky	n/a	None	None	None
Louisiana	By Statute and Rules: La. Rev. Stat. Ann. § 40:962.1 (1995); La. Admin. Code § 48:1.3945 (1995).	Prescription status with exemptions for specific product formulations in compliance with FDA; no exemption for single ingredient products.	Prescription status with exemptions for specific product formulations in compliance with FDA.	Prohibits advertising ephedrine for unapproved uses.

(Continued. . . .)

State	Type of Restriction, Citation and Date Enacted	Sales Restrictions on Single-Ingredient Ephedrine	Sales Restrictions on Combination Ephedrine Products	Other Restrictions on Ephedrine, PSE and PPA
Maine	n/a	None	None	None
Maryland	n/a	None	None	None
Massachusetts	n/a	None	None	None
Michigan	By Statute: Mich. Comp. Laws § 14.15(17766c) (1995).	None, but see limitation on large quantity purchases.	None, but see limitation on large quantity purchases.	Prescription required to possess more than 10 grams of ephedrine, whether single ingredient or in combination.
Minnesota	n/a	None	None	None
Mississippi	n/a	None	None	None
Missouri	By Statute: Mo. Rev. Stat. § 195.017.8(6) (1995). Mo. Rev. Stat § 195.246 and .248 (1996).	Controlled Substance Schedule IV (including combos with therapeautically insignificant quantities of other active ingredients).	None	Prohibits possession of ephedrine or pseudoephedrine with intent to manufacture methamphetamine; prohibits marketing of ephedrine or pseudoephedrine for unapproved uses.
Montana	By Statute: Senate Bill 8, to be codified at Mont. Code Ann. § 50-32-229(5) (1997).	Controlled Substance Schedule V (includes combos with therapeutically insignificant amount of other active ingredients).	None	Law expressly excludes dietary supplements containing ma huang.
Nebraska	By Statute: Neb. Rev. Stat. § 28-405 (1996).	Controlled Substance Schedule IV with exemp5tions for FDA-approved products (no exemptions for single ingredient).	Controlled Substance Schedule IV with exemptions for FDA-approved products.	None
Nevada	By Regulation: Nev. Admin. Code § 453.530(6)-(8) (revised 1994)..	Controlled Substance Schedule III, exemptions granted by brand name.	Controlled Substance Schedule III, exemptions granted by brand name.	None
New Hampshire	n/a	None	None	None
New Jersey	By Regulation: * (see note).	None, but limited to 50 mg. dose.	None, but limited to 50 mg. dose.	Prescription required for dosages of ephedrine of 50 mg. or more; smaller amounts may be OTC.

(Continued. . . .)

State	Type of Restriction, Citation and Date Enacted	Sales Restrictions on Single-Ingredient Ephedrine	Sales Restrictions on Combination Ephedrine Products	Other Restrictions on Ephedrine, PSE and PPA
New Mexico	By Regulation: Bd. Of Pharmacy Reg. No. 17 (1994).	Prescription required with exemption for lawful OTCs containing 00.5% or less of ephedrine.	Prescription required with exemption for lawful OTCs containing ephedrine in combination with other non-sympathomimetic active ingredient.	None
New York	Health Dept. Emergency order (1996).	None	None	Prohibits sale of specific list ephedrine-containing dietary supplements that make claims as "legal" stimulants.
North Carolina	n/a	None	None	None
North Dakota	By Regulation: * (see note).	None, but limited to 25 mg. dose.	None, but limited to 25 mg. dose.	Prescription required for doses of more than 25 mg. Doses 25 mg. or less are OTC.
Ohio	By Statute and Regulation: Ohio Rev. Code § 3719.44 and OAR § 4729-12-01 thru -10 (1994 & revised 1996).	Controlled Substance Schedule V for any produts containing ephedrine; exemptions granted by brand name by Bd. of Pharmacy, see regulations.	Controlled Substance Schedule V for any products containing ephedrine; exemptions granted by brand name by Bd. of Pharmacy, see regulations.	Law exempts pseudoephedrine and certain dietary products containing naturally existing ephedrine in ma huang.
Oklahoma	By Statute: Okla. Stat. § 2-210.A.34 (revised 1996).	Controlled Substance Schedule IV with list of exempted brand name products and criteria for further exemptions.	Controlled Substance Schedule IV with list of exempted brand name products and criteria for further exemptions.	Prohibits advertising of ephedrine for unapproved uses.
Oregon	By Regulation: Rule 885-80-022 and -028 (revised 1995).	Controlled Substance Schedule II; exemptions granted by brand name and blanket exemption for products approved for OTC sales by FDA.	Controlled Substance Schedule II; exemptions granted by brand name and blank exemption for products approved for OTC sales by FDA.	None
Pennsylvania	By Statute: 18 Pa. Cons. Stat. § 6316 (1997).	Unlawful to sell ephedrine to any person under 18 years old; exemptions for specific formulations in compliance with FDA and distributed for legitimate medicinal use in a manner to reduce likelihood of abuse.	Unlawful to sell ephedrine to any person under 18 years old; exemptions for specific formulations in compliance with FDA and distributed for legitimate medicinal use in a manner to reduce likelihood of abuse.	None

(Continued. . . .)

State	Type of Restriction, Citation and Date Enacted	Sales Restrictions on Single-Ingredient Ephedrine	Sales Restrictions on Combination Ephedrine Products	Other Restrictions on Ephedrine, PSE and PPA
Rhode Island	n/a	None	None	None
South Carolina	n/a	None	None	None
South Dakota	By Statute: S.D. Laws § 34-20B-19 (1995 and amended in 1997 by H.B. 1028). By Regulation: S.D. Admin. R. § 44:58:13:01 (1997).	Controlled Substance Schedule III.	Controlled Substance Schedule III: Dept. of Health exempts specific product formulations by regulation.	None
Tennessee	By Statute: Tenn. Code § 39-17-431 (1995).	Prescription status with exemptions for specific product formulations in compliance with FDA; no exemption for single ingredient products.	Prescription status with exemptions for specific product formulations in compliance with FDA.	Prohibits advertising ephedrine for unapproved uses.
Texas	n/a	None	None	None
Utah	n/a	None	None	None
Vermont	n/a	None	None	None
Virginia	By Statute: Va. Code Ann. § 18.2-248.5.	None	None	Ephedrine may not be sold, without prescription, to any minor in combination with caffeine.
Washington	By Regulation: WAC 246-883-030. By Statue: Wash. Rev. Code § 69.50 (1996).	Prescription status for any products containing ephedrine; exemptions granted by brand name.	Prescription status for any products containing ephedrine; exemptions granted by brand name.	Prohibits possession of ephedrine and pseudoephedrine with intent to produce methamphetamine.
West Virginia	n/a	None	None	None
Wisconsin	By Statute: Wisc. Stat. § 161.20(3)m. Wisc. Stat. § 961.01(12g) (1996).	Controlled Substance Schedule IV (includes combos with therapeutically insignificant quantities of other active ingredients).	None	Law clarifies that "isomers" of ephedrine include only optical isomer (not pseudoephedrine).
Wyoming	n/a	None	None	None

(Continued. . . .)

* A 1994 National Association of Boards of Pharmacy (NABP) newsletter has reported the restrictions on ephedrine indicated in New Jersey and North Dakota. However, a search of the administrative codes and subsequent phone calls to the boards of pharmacy in those states could not verify those restrictions or locate a statutory or regulatory citation for any such restriction. NDMA cannot confirm whether these restrictions do exist or were reported in error.

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